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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------------|---------------------|------------------|
| 10/500,411      | 06/24/2004  | Marie-Odile Galcera Contour | 427.088             | 4397             |

47888 7590 01/22/2007  
HEDMAN & COSTIGAN P.C.  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

|          |
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| EXAMINER |
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FREISTEIN, ANDREW B

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1626

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 01/22/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

74

|                              |                                 |  |  |
|------------------------------|---------------------------------|--|--|
| <b>Office Action Summary</b> | Application No.<br>10/500,411   | Applicant(s)<br>GALCERA CONTOUR ET AL. |  |
|                              | Examiner<br>Andrew B. Freistein | Art Unit<br>1626                       |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4 is/are rejected.
- 7) ☒ Claim(s) 5 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment filed 10/10/2006 was entered. Claims 1, 4, 5, 8-10 are pending. Claims 2, 3, 6, 7 and 11-15 were cancelled.

#### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Paragraph***

**(Pending)** Claims 1-8 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating human prostate cancer and human pancreatic cancer, the specification does not reasonably provide enablement for tumorous proliferative diseases, non-tumorous proliferative diseases, neurodegenerative diseases, parasitic diseases, viral infections, spontaneous alopecia, alopecia induced by exogenous products, radiation-induced alopecia, autoimmune diseases, transplant rejections, inflammatory diseases and allergies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

As a result of the amendment filed 10/10/2006, the rejection is withdrawn.

#### ***Double Patenting***

**(Pending)** Claims 1-6 and 8 were provisionally rejected on the ground of nonstatutory double patenting over claim 14 of copending Application No. 10/562,949. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. This rejection is maintained and made FINAL.

Applicant states that the amendment filed 10/10/2006 obviates the rejection. However, claim 14 of copending application 10/562,949 and the instant application

Art Unit: 1626

continue to have conflicting claims. As a result, the rejection is maintained and made final.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**(New)** Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On pages 4 and 5, variable R<sup>4</sup> states: "R<sup>4</sup> is selected from the group consisting of alkyl, cycloalkyl, cycloalkylalkyl, cyano and amino, alkyl and phenyl." It is unclear why "alkyl and phenyl" are listed at the top of page 5 and included in the definition of R<sup>4</sup>. Further, on page 5, variables R<sup>24</sup>, R<sup>25</sup> and R<sup>20</sup> are defined. However, there are no variables R<sup>24</sup>, R<sup>25</sup> and R<sup>20</sup> left in claim 1 after the amendment. In order to overcome this rejection, the following should be deleted from the top of page 5:

Art Unit: 1626

atom or an alkyl or and phenyl radical, and  $R^{24}$  and  $R^{25}$  ~~representing~~ are independently

alkyl radicals,

$R^{20}$  is hydrogen or alkyl,

### ***Claim Rejections - 35 USC § 102***

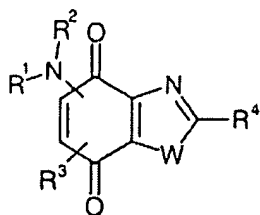
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

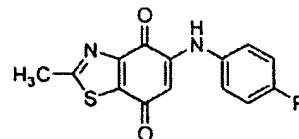
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**(New)** Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryu et al., "5-arylamino-2-methyl-4,7-dioxobenzothiazoles as inhibitors of cyclin-dependent kinase 4 and cytotoxic agents," Bioorganic & Medicinal Chem. Letters, Vol. 10, Iss. 5, pp. 461-464 (2000).

Claims 1 and 4 are drawn to a method of treating human prostate cancer or human pancreas cancer comprising administering a compound of formula (I),



, wherein  $R^1$  is H;  $R^2$  is aralkyl;  $R^3$  is H;  $R^4$  is alkyl; and W is S.



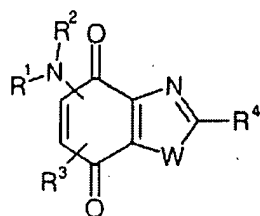
Ryu et al. disclose anti-cancer compounds of the formula

wherein R is H and CH<sub>3</sub> (see p. 462, Table 1; p. 461, col. 1).

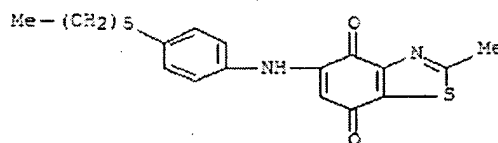
Art Unit: 1626

**(New)** Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryu et al., "Modulation of NAD(P)H:quinone oxidoreductase (NQO1) activity mediated by 5-aryl-amino-2-methyl-4,7-dioxobenzothiazoles and their cytotoxic potential," Archives of Pharmacal Research, Vol. 23, Iss. 6, pp. 554-558 (2000).

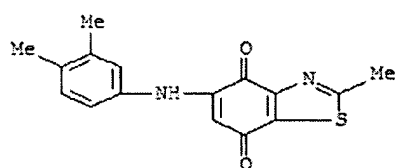
Claims 1 and 4 are drawn to a method of treating human prostate cancer or human pancreas cancer comprising administering a compound of formula (I),



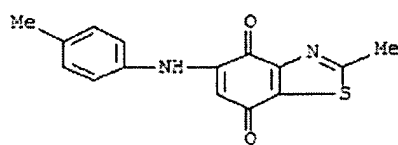
, wherein R<sup>1</sup> is H; R<sup>2</sup> is aralkyl; R<sup>3</sup> is H; R<sup>4</sup> is alkyl; and W is S.



Ryu et al. disclose the compounds:



and



(see Ryu et al., p. 555,

Table 1, compound nos. 3g, 3l and 3o).

### **Claim Objections**

Claims 5 & 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the rejected base claim and any intervening claims.

***Telephone Inquiry***

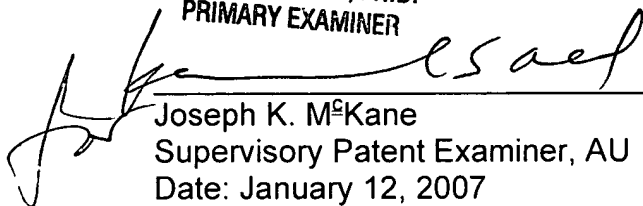
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>e</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER

  
Joseph K. M<sup>e</sup>Kane  
Supervisory Patent Examiner, AU 1626  
Date: January 12, 2007